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July 26, 2005

Division of Dockets Management (HFA-305) Food and Drug Administration Room 1061 5630 Fishers Lane Rockville, Maryland 20852

Re:

**Draft Guidance for Industry** 

Gingivitis: Development and Evaluation of Drugs for Treatment or

Prevention

FDA Docket No. 2005D-0240

70 Fed. Reg. 37102-37103 (June 28, 2005)

Enclosed are:

Volume I

Comment: Cosmetic Claims for Oral Antiplaque

**Products** 

Appendix A to

Volume I:

FDA Chief Counsel Opinion Letter

Volume II

Comment: Reduction and Prevention of Oral

Health Problems Claim in OTC Oral Antiplaque

**Drug Products** 

Volume III

Comment: Structure/Function Claim for OTC Oral

**Antiplaque Products** 

Appendix A to

Volumes II & III:

Bibliography

Appendix B to

Volumes II & III:

Clinical Study Reports (not included herewith)

Volume IV

**General Comments** 

3005D-02